

**AMENDMENTS TO THE DRAWINGS**

The attached revised sheets of drawings include changes to FIG. 7 and to FIG. 11. These sheets which include FIGS. 6 and 7 and FIGS. 10 and 11 replace the original sheets including FIGS. 6 and 7 and FIGS. 10 and 11. In originally filed FIGS. 7 and 11, the alphabetic designation of element numbers 114a and 114b had been omitted. In replacement FIGS. 7 and 11, element numbers 114a and 114b are consistent with the specification as originally filed.

Attachment: Replacement sheets

### **REMARKS/ARGUMENTS**

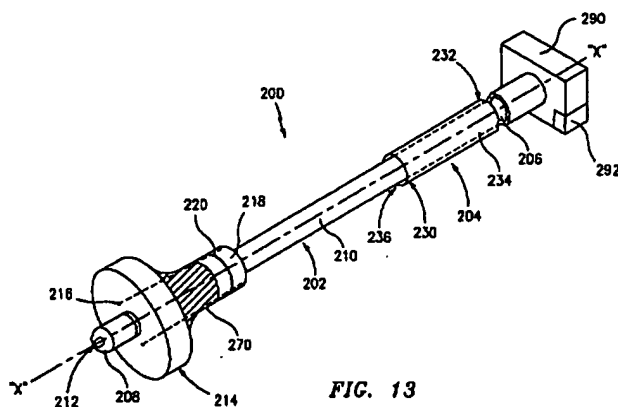
The present application has been reviewed in light of the Office Action dated July 31, 2008. Claims 1-10 and 12-44 are currently pending, of which claims 1 and 15 have been amended, and new claim 44 has been added. Claims 26-43 have been withdrawn, and claim 11 is cancelled herein. Applicant respectfully requests early and favorable reconsideration of this application.

Claims 1-2, 4, 6, 8-9, 12, 15-17, and 20-21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,176,864 to Chapman (hereinafter "Chapman"). Applicant respectfully submits that independent claims 1 and 15, as amended herein, are allowable over Chapman because Chapman fails to disclose the limitations of independent claims 1 or 15.

Pursuant to 35 U.S.C. § 102, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. Applicant respectfully submits that Chapman fails to disclose each and every element recited in independent claims 1 or 15, as required by 35 U.S.C. § 102.

Independent claim 1, as amended, recites a device for joining a first body vessel to a second body vessel including, *inter alia*, an expandable anchor having "a sheath disposed about [an] expandable anchor for defining the shape of the expandable anchor when in [an] expanded condition such that a distal end portion of the expandable anchor is radially larger than a proximal end portion of the expandable anchor in the expanded condition." In an embodiment of

the present application, as depicted in FIG. 13 below for example, a sheath 270 confines an anchor 214 to define a structural shape of the anchor 214. Sheath 270 provides a graduated proximal slope to facilitate positioning and alignment of the tissues to be joined as described in paragraph [0088]. In particular, sheath 270 may facilitate shaping of the anchor 214 such that anchor 214 may be configured for engagement with particular body vessels, such as bladder neck "N" and urethra "U" as described in paragraph [0097].



In contrast to claim 1, Chapman discloses an anastomosis device for connecting a graft vessel 10 to a target vessel 12 as depicted in FIGS. 8 and 9 below. The graft vessel 10 is inserted through a tubular member 20 (see col. 6, lines 38-45), and then a free end of the graft vessel is everted over an introducer 40 (see col. 6, lines 55-57). A graft coupling member 30 is compressed between the tubular member 20 and introducer 40 such that removing the introducer 40 permits the graft coupling member 30 to move to an expanded state (FIG 9).

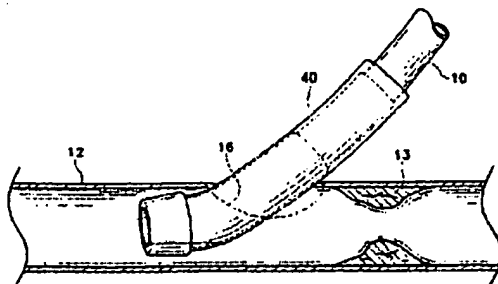


Fig. 8

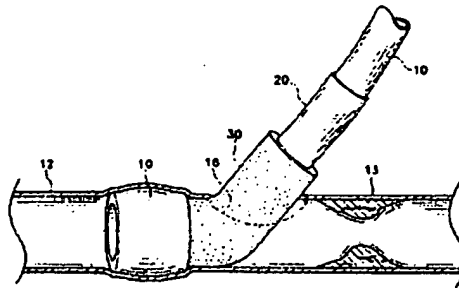


Fig. 9

In the expanded state, the graft coupling member 30 is uniformly expanded within the everted end of the graft vessel 10 to “apply a gentle circumferentially uniform, radial pressure against the inverted graft vessel” (col. 7, lines 47-49). The structural shape of graft coupling member 30 is therefore not defined by the graft vessel 10 such that a distal end portion is radially larger than a proximal end portion as required by claim 1.

In view of the foregoing, Applicant respectfully submits that the structure described in independent claim 1 is not taught, disclosed or contemplated by Chapman or the prior art references of record. Accordingly, Applicant respectfully submits that claim 1 is distinguishable over Chapman, and therefore allowable over Chapman under 35 U.S.C. § 102(b).

As claims 2, 4, 6, 8-9, and 12 depend from claim 1 and contain all of the features of claim 1, Applicant respectfully submits that claims 2, 4, 6, 8-9, and 12 are also allowable over Chapman under 35 U.S.C. § 102(b).

As indicated above, claims 15-17, and 20-21 also stand rejected under 35 U.S.C. § 102(b) as being anticipated by Chapman. Applicant respectfully submits that independent claim 15, as amended herein, is allowable over Chapman because Chapman fails to disclose the limitations of independent claim 15.

Independent claim 15, as amended, recites a device for performing a surgical anastomosis of a first body vessel and a second body vessel, including, *inter alia*, a radially expandable anchor including a proximal end portion “configured for exerting a radially outward force on at least one of the first and second body vessels.” As indicated above, a proximal end portion 114b of expandable anchor 114 extends into the urethra “U” and exerts a radially outward force thereupon (see paragraph [0072]). In contrast to claim 15, the proximal end of the graft coupling member 30 of Chapman extends out of the target vessel 12 and radially surrounds the graft vessel 10. Therefore, the proximal end of graft coupling member 30 does not exert a radially outward force on either the target vessel 12 or the graft vessel 10, but instead exerts a radially inward force on the graft vessel 10.

In view of the foregoing, Applicant respectfully submits that the structure described in independent claim 15 is not taught, disclosed or contemplated by Chapman or the prior art references of record. Accordingly, Applicant respectfully submits that claim 15 is distinguishable over Chapman, and therefore allowable over Chapman under 35 U.S.C. § 102(b).

As claims 16-17, and 20-21 depend from claim 15 and contain all of the features of claim 15, Applicant respectfully submits that claims 16-17, and 20-21 are also allowable over Chapman under 35 U.S.C. § 102(b).

Claims 3 and 19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Chapman in view of U.S. Patent No. 2,898,913 to Ritter et al. (hereinafter Ritter). Applicant submits that claims 3 and 19 are allowable under 35 U.S.C. § 103(a) over Chapman in view of Ritter.

The Examiner relies on Ritter for the disclosure of an anchor having a frusto-conical shape. Ritter relates generally to a hemostatic cone for insertion into the fossal cavity to enhance the healing process following a prostatectomy (see col. 1, lines 15-20). Applicant submits that even if Ritter does disclose an anchor having a frusto-conical shape, Ritter fails to cure the deficiencies of Chapman in that Ritter does not disclose “a sheath disposed about the expandable anchor for defining the shape of the expandable anchor when in the expanded condition” as recited in independent claim 1. Also, Ritter does not disclose a “radially expandable anchor including a proximal end portion configured for exerting a radially outward force on at least one of the first and second body vessels and a distal end portion for exerting a radially outward force on the other of the first and second body vessels,” as recited in independent claim 15.

Accordingly, in view of the foregoing, since Ritter fails to cure the deficiencies of Chapman, Applicant submits that claims 3 and 19 are allowable under 35 U.S.C. § 103(a) over Chapman in view of Ritter.

Claims 5, 13, 14, 18 and 25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Chapman in view of U.S. Patent No. 5,411,520 to Nash et al. (hereinafter Nash). Applicant submits that claims 5, 13, 14, 18 and 25 are allowable under 35 U.S.C. § 103(a) over Chapman in view of Nash.

The Examiner relies on Nash for the disclosure of a plug that expands upon contact with moisture. Nash relates generally to a system for sealing a percutaneous puncture in a blood vessel and discloses a collagen plug 30 that expands in the presence of blood (see col. 7, lines 1-4). Applicant submits that even if Nash does disclose a plug that expands upon contact with moisture, Nash fails to cure the deficiencies of Chapman in that Nash does not disclose “a sheath

disposed about the expandable anchor for defining the shape of the expandable anchor when in the expanded condition” as recited in independent claim 1. Also, Nash does not disclose a “radially expandable anchor including a proximal end portion “configured for exerting a radially outward force on at least one of the first and second body vessels and a distal end portion for exerting a radially outward force on the other of the first and second body vessels,” as recited in independent claim 15.

Accordingly, in view of the foregoing, since Nash fails to cure the deficiencies of Chapman, Applicant submits that claims 5, 13, 14, 18 and 25 are allowable under 35 U.S.C. § 103(a) over Chapman in view of Nash.

Claims 7 and 22-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Chapman in view of U.S. Patent No. 6,241,743 to Levin et al. (hereinafter Levin). Applicant submits that claims 7 and 22-24 are allowable under 35 U.S.C. § 103(a) over Chapman in view of Levin.

The Examiner relies on Levin for the disclosure of an anastomosis device defining a porous structure. Levin relates generally to a device for creating an end to side anastomosis having a generally tubular structural member 12 (see col. 4, line 64) with a porous region 26 (see col. 5, lines 63-67). Applicant submits that even if Levin does disclose a tubular member with a porous region, Levin fails to cure the deficiencies of Chapman in that Levin does not disclose “a sheath disposed about the expandable anchor for defining the shape of the expandable anchor when in the expanded condition” as recited in independent claim 1. Levin also fails to disclose a radially expandable anchor including a proximal end portion “configured for exerting a radially outward force on at least one of the first and second body vessels and a distal end portion for

exerting a radially outward force on the other of the first and second body vessels,” as recited in independent claim 15.

Accordingly, in view of the foregoing, since Levin fails to cure the deficiencies of Chapman, Applicant submits that claims 7 and 22-24 are allowable under 35 U.S.C. § 103(a) over Chapman in view of Levin.

Claim 10 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Chapman, or in the alternative under 35 U.S.C. § 103(a) as being unpatentable as obvious over Chapman. Applicant submits that claim 10 is allowable under both 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) over Chapman in view of the amendments and remarks presented above with regard to claim 1. Since claim 10 depends from claim 1, and since, as discussed above, Chapman fails to disclose an expandable anchor having “a sheath disposed about the expandable anchor for defining the shape of the expandable anchor when in the expanded condition” as recited in claim 1, Applicant respectfully submits that claim 10 is allowable over Chapman.

Newly presented claim 44 depends from independent claim 15, and relates to an expandable anchor configured for exerting a radially outward force along substantially its entire length. Applicant respectfully submits that claim 44 is allowable over the prior art of record.

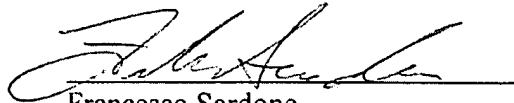
In view of the amendments made to the claims herein, and in view of the remarks and arguments presented above, it is respectfully submitted that each of the rejections raised by the examiner in the present Office Action have been overcome. It is respectfully submitted that none of the references of record, considered individually or in any proper combination with one another, disclose or suggest the present invention as claimed.



Should the Examiner believe that a telephone interview may facilitate prosecution of this application, or resolve any outstanding matters, the Examiner is sincerely invited to contact the Applicant's undersigned representative at the number indicated below.

In view of the foregoing amendments and remarks, reconsideration of the application and allowance of claims 1-10, 12-25 and 44 is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Francesco Sardone', written over a horizontal line.

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